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| 10/048,185 | 06/17/2002 | Pascual Perez | 34934-PCT-USA<br>072667.0180 | 2915 |

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| EXAMINER | |
|---|---|
| ROBINSON, KEITH O NEAL | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/048,185 | PEREZ ET AL. | |
| | Examiner | Art Unit | |
| | Keith O. Robinson | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-12 and 14-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 and 14-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/7/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United States of America on June 17, 2002. It is noted, however, that applicant has not filed a certified copy of the 99/09990 application as required by 35 U.S.C. 119(b).

### *Specification*

The disclosure is objected to because of the following informalities:

Page 9, paragraph 15 is objected to because the specification discloses a primary transformant "with the expected phenotype". This phenotype is not disclosed in the claims nor is it explained in the specification. The applicant is asked to explain/describe said phenotype. New matter should be avoided.

Page 26 of the specification has improper labeling. The description of Figures 1 and 2 are under the title "Legend of the Figures". The specification must include a section entitled "Brief Description of Drawings" which includes a description for each figure of the drawings.

A reference to Figure 3 is disclosed in the specification but the actual figure is missing from the specification.

### *Claim Objections*

Claim 16 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim, such as claim 12. See MPEP § 608.01(n). In the interest of compact prosecution, claim 16 has been examined. Such treatment does not relieve Applicant of the responsibility to respond to this objection.

### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-12 and 14-16 are broadly drawn to methods of producing isotransgenic plants of any species, using hybrids produced by crossing any "line suited to transformation" of any genotype with any "line of interest" of any genotype, including any "commercial elite line" (claim 9), and the resultant plants (claims 11-12 and 16). The claims are broadly drawn to any unspecified number of backcrosses, any method of

identifying genomic DNA sequences (claims 2-3 and 10) including RFLP or any "sequencing method" (claim 3), any transgene conferring any property including improved agronomic properties and/or disease resistance (claim 7). The claims are broadly drawn to the omission of any fragment linked to the transgene which "may be the subject of a genetic burden" (claim 9).

In contrast, the specification only provides guidance for using a single maize genotype, A188, as the "line suited to transformation", and only mentions RFLP techniques in any detail. The specification demonstrated that the only transgene insertion in the originally transformed hybrid actually occurred in the genome of the non-agronomic A188 parent (see, page 48 of the specification, lines 10-12). No guidance is provided regarding the identification of any other "line suited to transformation" from maize or any other crop, any other type of "sequencing method" to assay molecular markers, any transgene which confers improved agronomic properties or which simultaneously improves agronomic properties and improves disease resistance. Even for the single exemplified RFLP method, no guidance is provided regarding the actual assay conditions or probes used.

The specification does not teach in detail how selection of transformants, which have integrated the transgene onto the genome of interest, is determined. The specification discloses that the Southern technique "may in particular be used to identify and characterize the insertion into the genome of the plant, thus making it possible do differentiate the transformation events". However, the specification also discloses "the protocol described in Sambrook et al. (1989) may be used". It is not clear from the

specification which technique is being used in the claimed invention and the techniques are not described in a manner that would allow one of ordinary skill in the art to use the invention. For example, the specification states using the Southern technique with several restriction enzymes and several suitable probes, but fails to describe or identify such enzymes and probes (see page 31, paragraph 15 and page 32, paragraph 15).

The method of identifying the genomic sequences adjacent to the inserted T-DNA is not fully disclosed as claimed in the invention (see, Claim 2). The specification mentions the use of the commercial Universal GenomeWalker kit; however, the detailed steps are not described. Also, mention is given to "other enzymes specific for restriction sites with 4 or 5 bp", but these enzymes are not described (see, page 34, paragraph 10).

The identification of the recipient parent is not disclosed in detail. The specification does not describe the RFLP technique or the sequencing method in detail as claimed in the invention (see, Claim 3). The specification discusses "various restriction enzymes" but does not describe or name these enzymes and also does not describe the type of electrophoresis gel that was used (see, page 37, paragraph 25).

The specification does not teach an isotransgenic line that has the genotype entirely of the line of interest nor does it describe the said line of interest as claimed in the invention (see, Claim 4). Also, the genetic background and origin of this genotype is not disclosed.

The specification does not disclose a second line of interest as claimed in the invention (see, Claims 5 and 14) and very broadly claims "a crop plant, vegetable plant,

and a floral plant" (see, Claim 6). These terms are very broad and are not defined in the specification and therefore would not allow one who is skilled in the art the ability to use the claimed invention. Also, the specification does not fully disclose a protein which confers agronomic properties and/or properties of resistance to disease (see, Claim 7), a commercial isotransgenic line (see, Claim 8), or an isogenic plant that is substantially free of fragments linked to the transgene (see, Claim 9).

Claim 15 claims maize, wheat, rapeseed, sunflower, pea, soybean, and barley but the specification only discloses maize. The claimed plants represent different genera and are structurally, morphologically, and physiologically different from each other.

Finally, no truly isotransgenic plant line is actually demonstrated which is free or "substantially free" of linked fragments which "may be the subject of a genetic burden". Applicant merely provides suggested protocols for the number of backcrosses needed to produce such a plant, given the assumption of a particular number of available molecular markers.

The creation of a truly isotransgenic plant line with no linked unwanted genetic material is unpredictable. It is extremely difficult to minimize the linkage of a transgene with unwanted genetic material from a non-agronomic parent, when transforming a hybrid derived from a transformable, non-agronomic parent crossed with a less transformable, agronomic parent. See the paragraph bridging pages 4 and 5 of the specification. Zeven et al. (Euphytica 32: 319-327, 1983) teach that linkage drag is very common in backcross breeding (see, pages 325-327) and Young and Tanksley

(Theoretical and Applied Genetics 77: 353-359, 1989) teach that "backcross breeding is only moderately effective in reducing linkage drag around gene targets" (see, page 357, column 1, second full paragraph). Thus, individual progeny plants with substantial amounts of genetic material from the non-agronomic parent will have lost many of the agronomic traits of the agronomic "line of interest", and it is unclear which useful traits will be retained, particularly in a plant with as much as 25% of unwanted genetic material as claimed in claim 4.

Furthermore, even if 99% of the genome of the agronomically suited parent is obtained following backcrossing, it is impossible to obtain truly isotransgenic lines if the transgene were originally inserted into the non-agronomic parent (see page 24 of the specification, lines 15-19). As transformability is genotype-dependent, and as transformable "hotspots" are known to occur in particular genomic regions, transgene insertion into genomic regions of a hybrid derived from the genome of an untransformable genotype is unlikely. Thus, it is more likely that the transgene would be inserted into the genomic region derived from the non-agronomic, transformable parent. Due to linkage drag, it is unpredictable and unlikely that the linkage between the transgene and the unwanted genetic material could be broken.

In addition, the creation of any truly isotransgenic plant line depends upon a large number of molecular markers to facilitate selection and minimize the number of backcross generations needed, as well as to minimize the number of crosses to be made in each backcross generation. See the tables on pages 43 and 45. It is unclear that the broadly claimed genus of any plant species, including any crop, vegetable or

floral species, is sufficiently well characterized with respect to type and number of molecular markers to enable efficient backcrossing and selection of a truly isotransgenic plant. Staub et al. (HortScience 31(5): 729-741, 1996) teach that marker systems differ in their use across populations, species, and genera, and their efficiency in the detection of polymorphisms (see, page 731, third column, second full paragraph).

Furthermore, even with a particular type of well-defined molecular marker technique, the recovery of pertinent molecular markers is unpredictable and unlikely, unless proper reaction conditions are utilized. See, e.g., Welsh and McClelland (Nucleic Acids Research 18(24): 7213-7218, 1990) who teach that the use of a single primer and unspecific reaction conditions resulted in the recovery of a multitude of non-pertinent genetic material across divergent bacterial and plant species (see, page 7216, column 2, fourth paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to obtain a multitude of molecular markers in a multitude of crop plant species, to utilize a multitude of different types of molecular markers and molecular marker assay techniques under a multitude of unspecified reaction conditions, to utilize a multitude of unspecified parents comprising a "line of interest" and a "line suited to transformation" of any genotype, and to utilize a small unspecified number of backcrossing generations, to obtain truly isotransgenetic plant lines with substantially no unwanted genetic material derived from the "line suited to transformation". Furthermore, undue experimentation would have been required to evaluate and determine the actual use of

"pseudoisotransgenetic" plant lines with substantial amounts of unwanted genetic material from the non-agronomic parent plant, as particularly claimed in claim 4.

Claims 11-12 and 16 are drawn to products of the methods to produce isotransgenic plants.

The claims appear to employ novel plants derived from the crossing of parental lines of which are a line of interest and a line suited to transformation. Since the plants are essential to the claimed inventions it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants

may provide assurance of compliance by an affidavit or declaration, or by at statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807)l and,

(e) the deposit will be replaced if it should ever become inviable.

Claims 1-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to methods of producing isotransgenic plants of any species, using hybrids produced by crossing any "line suited to transformation" of any genotype with any "line of interest" of any genotype, including any "commercial elite line" (claim 9), and the resultant plants (claims 11-12 and 16). The claims are broadly

drawn to any unspecified number of backcrosses, any method of identifying genomic DNA sequences (claims 2-3 and 10) including RFLP or any "sequencing method" (claim 3), any transgene conferring any property including improved agronomic properties and/or disease resistance (claim 7). The claims are broadly drawn to the omission of any fragment linked to the transgene which "may be the subject of a genetic burden" (claim 9). In contrast, the specification only discloses a single maize "line suited to transformation" and does not disclose the "line of interest" or the "commercial elite line". Furthermore, there is no reference as to the genetic or morphological description of these lines. There is also no description of the types of molecular markers used in the specification. Though there is reference to the use of RFLPs, the exact markers that are used are not described nor is the size of these markers given.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of , is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the molecular markers or of the genotypes or phenotypes of the parents of a hybrid used in making an isotransgenic plant. Given the lack of written description of the molecular markers or parent materials used in producing an isotransgenic plant, any of the other methods and products from such methods would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-12, and 14-16 are rejected as they are vague and do not distinctly claim the subject matter which the applicants regard as their invention. Dependent claims are included in all rejections.

In Claim 1, part (d) "each backcross until" is confusing as it is unclear whether "each" refers to the particular individual progeny of a single backcross generation, the progeny from a number of successive backcrosses, or both. If successive backcrosses were intended, as recited at the bottom of page 3 in the specification, the claim should be amended to so indicate.

The "isogenic plant" in claim 9 lacks antecedent basis in claim 1, which recites an "isotransgenic plant".

In claim 16, the "hybrid according to claim 12" is confusing, since claim 12 is drawn to an isotransgenic line produced from a hybrid, rather than a hybrid per se.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragot et al. (Techniques et utilisations des marqueurs moleculaires ; Montpellier (France) 29-31 mars 1994 ; Ed. INRA, Paris 1995 (Les Colloques, n72) ; pages 45-56).

The claims are broadly drawn to isotransgenic plants or lines or hybrids produced by methods for production of isotransgenic plants that consist of (1) transformation of hybrid plants with a vector containing a transgene; (2) selection of plants with transgene; (3) backcrossing selected plants with the agronomically desirable parental line followed by further selection.

Ragot et al. teach the introgression of a transgene construct from a transformed corn plant into an elite inbred corn line via backcrossing to the elite inbred line. They also teach the selection of plants carrying the transgene at each generation and the use of RFLPs to establish genotypes of the plants in each generation (see pages 46-47) wherein an isotransgenic plant containing the transgene but otherwise maintaining the genotype of the elite inbred was obtained (see page 55).

The isotransgenic corn plants taught by Ragot et al. differ from the claimed corn plants only in their method of making; namely, the incorporation of the plant transformation step before or after the initial hybridization step, and in the use of T-DNA versus particle bombardment as the transformation vehicle. However, the method of making an isotransgenic corn plant, which contains a transgene but otherwise contains the complete genome of an agronomically desirable inbred, would not confer a patentable distinguishing characteristic to the isotransgenic plant itself. It is well known

in the art that part or all of the 25 base pair T-DNA borders may not be incorporated into the plant genome, particularly the left border. Any fraction of the 25 base pair T-DNA border integrated into the plant genome would be indistinguishable from a linker or other sequence found on the vector used to produce the transformed plants of Ragot et al.

See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See also In re Best, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al. (Nature Biotechnology, 14: 745-750, June 1996) in view

of Does et al. (Plant Molecular Biology 17: 151-153, 1991), Hiei et al. (Plant Journal 6(2) 271-282, 1994), Armstrong et al. (Theoretical and Applied Genetics 84: 755-762, 1992), and Ragot et al (Techniques et utilisations des marqueurs moleculaires ; Montpellier (France) 29-31 mars 1994 ; Ed. INRA, Paris 1995 (Les Colloques, n72) ; pages 45-56).

Ishida et al. teach the transformation of hybrid plants comprising the parental line of which are, a line suited for transformation (A188) and a line of interest (five different inbred lines) through the use of Agrobacterium (see, pages 745-747). They do not teach selection of hybrid primary transformants having the integrated T-DNA or the backcrossing of selected hybrid primary transformants with the parental line of interest. They also do not teach the selection of at least one transgenic individual derived from each backcrossing until an isotransgenic line is produced.

Does et al. teach a method of obtaining one integrated T-DNA in the genome of tobacco 10 weeks after transformation by using inverse polymerase chain reaction (IPCR) to amplify plant genomic DNA sequences flanking the known T-DNA sequences (see, pages 151-153).

Hiei et al. teach a method of producing transgenic rice plants by co-cultivation of monocotyledonous rice tissues with *Agrobacterium tumefaciens* and the analysis of the plant genomic DNA sequences flanking T-DNA using PCR (see, pages 279-281). They also report the use of a super binary vector that confers high frequencies of transformation.

Armstrong et al. teach the method of transforming cells of hybrid plants and the backcrossing of said plants to recurrent parent (see, pages 756-757). They disclose a

backcrossing program initiated by establishing Type-II cultures from immature $F_2$ embryos from a sib-pollinated A188 x B73 plant. The regenerated plant from one $F_2$ culture was crossed with the recurrent parent (B73) to produce $BC_1$ population. $BC_1$ plants were selfed and immature embryos were placed in culture and plants were regenerated from the culture. One plant from this culture was used to cross with the recurrent parent (B73) to produce $BC_2$ population. This procedure was repeated to produce a $BC_3$ population, which was simultaneously self-pollinated and backcrossed. Their results demonstrate the effectiveness of backcrossing in improving the culture response to an elite variety. In addition, Armstrong et al. teach the use of RFLP analysis in identifying the locations and effects of the introgressed A188 chromosomal regions.

Ragot et al. teach the desirability of isogenic maize lines containing a gene of interest, but otherwise maintaining the genome of an elite agronomic line, including the use of transgenes conferring agronomic properties as the introgressed gene (see, page 45, second paragraph; page 46, third full paragraph; page 55, first full paragraph).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made would to have used the method of Ishida et al. to transform hybrid plants and to modify that method by incorporating that of Does et al. and Hiei to assay the T-DNA integrated into the genome of said plants and furthermore, to use the backcrossing and RFLP method of Armstrong et al. to develop isotransgenic plants containing a desired transgene; given the desirability of isogenic transgenic lines and success in obtaining them as taught by Ragot et al.

Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

***Summary***

No claims are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918 and whose email address is keith.robinson@uspto.gov. However, the office cannot guarantee security through the email system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 21, 2004

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638